INTERNATIONAL STANDARD

IEC 60601-1

Third edition
2005-12

Medical electrical equipment –

Part 1:
General requirements for basic safety and essential performance

*This **English-language** version is derived from the original **bilingual** publication by leaving out all French-language pages. Missing page numbers correspond to the French-language pages.*

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Fuseholders where the fuselink is held in a cap that can be removed without use of a TOOL are a special concern. If the fuselink does not come out when the cap is removed, the OPERATOR could be inclined to try to remove it by gripping the end of the fuselink with the fingers. The OPERATOR could try to insert a new fuselink into the fuseholder without first inserting it in the cap. Both cases can be considered reasonably foreseeable misuse. This should be taken intoconsideration with assessing what parts are accessible.

The reader is referred to IEC 60127-6 [7] for more information on fuseholders.

Clause 6 – Classification of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT can have a multiple classification.

Subclause 6.2 – Protection against electric shock

The term “Class III equipment” is used in some other standards to identify equipment that is powered from a safety extra-low voltage (SELV) mains supply system. The term Class III equipment is not formally used in this standard. The BASIC SAFETY of Class III equipment is critically dependent on the installation and on other Class III equipment connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for ME EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons, this standard does not recognize Class III construction.

Subclause 6.3 – Protection against harmful ingress of water or particulate matter

It should be noted that compliance with the requirements of this standard automatically allows MANUFACTURERS to rate ME EQUIPMENT as IP2X because the requirements of IEC 60529 for this rating are the same as the accessibility requirements (see 5.9).

Subclause 6.6 – Mode of operation

CONTINUOUS OPERATION and non-CONTINUOUS OPERATION cover the range of operating modes of virtually all equipment. ME EQUIPMENT that remains plugged into the SUPPLY MAINS continuously but is operated intermittently should be RATED for non-CONTINUOUS OPERATION, have the appropriate indication of on/off times in the ACCOMPANYING DOCUMENTS and markings on the ME EQUIPMENT (see 7.2.11).

Subclause 7.1.1 – USABILITY of the identification, marking and documents

For ME EQUIPMENT to be well designed, its markings and ACCOMPANYING DOCUMENTS should be clear, consistent, and help to reduce potential use error. Thus, markings and ACCOMPANYING DOCUMENTS should undergo the same rigorous evaluation as other OPERATOR-ME EQUIPMENT interface elements.

Subclause 7.1.2 – Legibility of markings

Markings on ME EQUIPMENT are expected to be CLEARLY LEGIBLE by an OPERATOR over the range of normal illumination levels where the ME EQUIPMENT is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design [51]:

Subclause 11.6.2 – Overflow in ME EQUIPMENT

The purpose of this test is to assess not only whether the liquid actually wets any parts in a way that would adversely affect a MEANS OF PROTECTION or result in a HAZARD; but also whether a similar amount of liquid that could overflow on another occasion and reach the same parts of the ME EQUIPMENT, but possibly not land in exactly the same way, could adversely affect a MEANS OF PROTECTION or result in a HAZARD. The results of the test should be evaluated to assure they realistically represent conditions that will be experienced when the ME EQUIPMENT is used.

Subclause 11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

In addition to ME EQUIPMENT that requires the use of fluids, many types are exposed to fluid spills as part of their REASONABLY FORESEEABLE MISUSES. In such cases (as well as for ME EQUIPMENT requiring fluids) the amount and location where spills can occur vary greatly. Only a proper evaluation of the ME EQUIPMENT being tested can determine an appropriate application of the requirement. Doing such an evaluation is the responsibility of the MANUFACTURER and the results are to be provided to those performing the test (typically in the RISK MANAGEMENT FILE). This requirement would be an appropriate area for evaluation by writers of particular standards.

Examination of the NORMAL USE of ME EQUIPMENT should provide an adequate estimate of the amount of fluid that is likely to be spilled on it.

Spillage for equipment that does not require the use of fluids is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.4 – Leakage

Leakage is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS

Although it is unlikely that ME EQUIPMENT would be RATED for protection against particulate matter, IEC 60529 does address the possibility and it should be considered a valid option. The presence of any water or particulate matter inside the ENCLOSURE after testing in accordance with its IEC 60529 classification is regarded as a NORMAL CONDITION. The requirement is therefore to assess the possibility of a HAZARDOUS SITUATION due to such ingress in combination with a possible SINGLE FAULT CONDITION (such as an interrupted PROTECTIVE EARTH CONNECTION).

Subclause 11.6.8 – Compatibility with substances used with the ME EQUIPMENT

ME EQUIPMENT, ACCESSORIES and parts thereof should be designed to be used safely with the substances with which they are intended to come into contact in NORMAL USE.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 11.8 – * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Interruption of the power supply could result in a HAZARD due to loss of functionality. This HAZARD is dealt with in 7.9.2.4. Restoration of the power source can also result in HAZARDOUS SITUATIONS. Examples could include unintended activation of moving parts or resumption of dangerous outputs. These potentially HAZARDOUS SITUATION and the duration of the power interruption that could result in the HAZARDS need to be considered as part of the RISK MANAGEMENT PROCESS.